March 7, 2014

OTC Ophthalmic Drug Products – Emergency Use Eyewash Products, Public Hearing

Dr. Kweder and FDA Panel

Thank you for having this discussion and the opportunity to share observations.

I started my business in 1968 and have made eyewash since the mid 1990's. I supply it in the EU, Australia, Canada and the USA.

My comments are centered about your five questions for the scope of this meeting.

However; the starting point is with ANSI Z358.1 which sets out terminology of Plumbed and Portable eyewash stations. The standard also uses qualifiers as self-contained and gravity-fed.

Continuing with that reference or language since it is commonplace in industry, there are three types of Portable, Self-contained, Gravity-fed Eyewash Stations in use to-day, listed historically:

A. **Empty** Eyewash Stations and optional Eyewash Water Preservative
B. **Refillable** Eyewash Stations
C. **Non-refillable** Eyewash Stations

The above three I believe are what is referred to as Large Volume in your document and the second configuration identified as *concentrated solutions and additives,* I suggest, is not another general configuration within Large Volume EE products.

Rather, Eyewash Water Preservatives are an essential ingredient or component for #A, the Empty Eyewash Station.

I disagree with the idea that 349.20 does not include conditions of use for the EE products which can only be Small Volume just because the Large Volume or Portable, Self-contained, Gravity-fed Eyewash Stations are regulated by ANSI Z385.1.

Small Volume bottles are retailed by most if not all safety supply distributors. Chemical burns are not limited to the workplace. NSC 2011 reported 30% happen at home.

But 349.3(a) (f) names, *without exception*, aqueous solution intended for flushing the eye. Need we or are we re-inventing the wheel with 349.22?

I suggest that only the language change to include the improved focus on containers - 16 fl.oz. and larger - to address the first aid treatment of chemical burns. Emphasis on the *first aid treatment* since the marketplace has created that option with prepackaged containers of eyewash, Z358.1 compliant.

Why limit the EE Product group to 32fl.oz? Let's build on the products developed for ANSI standards, everyone's goal is the 15 minute flush.

This is the opportunity to bridge the regulatory gap with Z385.1.

The irrigating solution concerns for safe & effective are best managed and understood in the Drug supply side while the body of knowledge developed over the years through ANSI to make an efficient and dependable delivery system for the 15 minutes flushing combined meets all concerns, and best left with ANSI.

ANSI would require additions to the Definitions table to accommodate their Personal Bottle of eyewash and the applicable FDA role as that Regulator. That is only from my perspective without any knowledge of ANSI.

Re-fillable Eyewash Stations and Non-refillable Eyewash Stations did not exist in 1988, to my knowledge.

We don't have the option to improve the first aid treatment aspect but for the maintaining the pH within a range of 6.6 and 7.4 suggested in 349.22 with Empty Eyewash Stations with eyewash water preservatives currently on the market.

Why limit the container size to 32 fl oz. when the *new* normal offers the ideal 15 minute flush?

Related query is why add 349.22? What does it offer that is lacking in 349.20?

Yes, buffering to correct the pH of the eye to a safe range and to stabilize any changes in the pH and with saline to physiologically correct the saline content are valuable but not essential. But why not?

Why limit the “treatment” to just balancing the osmotic pressure of eye fluids?

349.22 is different but is it better and is it necessary from a supply point?

I suggest that it is not, in fact a step backwards. You have the toughest and most comprehensive standard worldwide, keep it.

Eyewashes in the market, compliant with 349.20 are offering better formula and improved containers compared to 1988.

Question 1.

Type A. Empty Station requires potable water plus an eyewash water preservative to meet the USP 30 <51> Category 1 preservative challenge test based upon the service life claimed on the label.

Type B. Re-fillable Stations & Type C. Non-refillable Stations require eyewash solution per §349.20 alternatively, irrigating water quality per USP sterile water for Irrigation.

The function never changes from flushing foreign matter from the injured eye.

Small Volume EE products should meet the Monograph §349.20. Please see the attached list of Small Volume products ingredients per the label claim.

Question 2.

Large Volume Stations

If I correctly understand Z 358.1 the three types, A, B & C do not require activation, just a visual inspection to verify adequate fluid level. This is not the case for Plumbed stations. Nor could I find that Type A Empty eyewash Station required a preservative.

Self-contained stations, all three types are incubators: Z 358.1 required

- 60°F minimum temperature
- no direct sunlight
- valves/hoses dormant for up to one year

Empty Stations, Type A, have vented caps. What are the variables in the air quality environment on site?

Question 3.

USP 30 <51> Category 1 (ophthalmic products) does not test for Acanthamoeba. It does test for the bacterium E.coli and Staph plus fungus Candida albicans and Aspergillus brasiliensis.

The common label claim is six (6) months for the stations described above. Is the efficacy based upon “use” water at 173 days? Where is the performance standard for Maintenance? With the station manufacturer or with the eyewash water preservative manufacturer?

Season temperatures, season water run-off impact on local drinking water, and the air quality at the workplace are variables impacting and impeding the safe and effective irrigation expected from the emergency eyewash station.

Question 4.

Potable water, unpreserved will not meet the USP 30 <51> Category 1 Antimicrobial Effectiveness Test.

Question 5.

All Small Volume EE products are sterile per their label.

Question 6.

Large Volume type A. Empty Eyewash Station directions for use are well done for the most part. Weekly testing of the flushing action and replacing the solution with potable water are critical to insure it works when needed.

From my personal experience, I seek confirmation that eyewash water preservatives are properly classified inactive drugs in §207.10(e) for labeling, while; at the same time, a drug in 21 USC 321 Section 201(g)(1)(D) as a component used with a drug product defined by the intended use.

Thank you.

Ed Maloney

T.E.Maloney, Agent

1527133 Ontario Limited

Importer of Record

t.e.maloney@1527133ontariolimited.biz Telephone +1 905 901 3355